Magnetic Resonance Imaging (MRI) Services
Proposed Revisions to MRI Definitions & Criteria dated 10/15/03
(Initial Draft)

Note: Prepared March 11, 2004. Annotations (highlighted) reflect general comments provided by THA Workgroup Members and HSDA staff from November 2003 to Current.

PROPOSED DEFINITIONS

Magnetic Resonance Imaging: MRI is a noninvasive diagnostic imaging procedure that uses radio waves, high magnetic fields and a powerful computer to create diagnostic images to detect and assess disease states. Nuclei of atoms in various structures of the body resonate differentially when exposed to a strong magnetic field. MRI devices register these differences in response as images without the use of ionizing radiation such as X-Rays, or iodinated compound injections. The spatial resolution produced by MRI results in a two-dimensional picture with great tissue contrast, clarity and potential to characterize tissue as diseased or not diseased.

MRI equipment can be installed as stationary or fixed units and can also be transported as a mobile equipment service. Initial MRI scanners incorporated a "closed bore" design. The current generation of MRI units offers improvements in magnetic field strength, processing times, image resolution and the introduction of an "open bore" scanner design.

Due to the multiple numbers of diagnostic applications, the quality of the images produced and the relative safety of the procedure, MRI has rapidly become what many physicians refer to as the "gold standard" of diagnostic imaging. Organ systems suitable for MRI examination include: brain, spinal column, respiratory, circulatory, cardiac, breast, abdomen, kidney and pelvis, musculoskeletal, and blood vessels. As of March 2003, the Centers for Medicare and Medicaid Services (CMS) has approved 55 of 60 total common procedure terminology code (CPT codes) MRI applications for participating freestanding facilities in the United States.

Mobile MRI Scanner means a MRI scanner and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States. (Revised December 2003)

THA Workgroup Comments: Staff's 10/15/003 draft proposal discussed the potential of documenting CT patient referrals or CT utilization in service areas where no MRI units exist. Members attending the 11/07/03 THA Workgroup meeting questioned the clinical relevance of CT utilization to measure potential MRI utilization. The members opined that documentation regarding MRI referrals should be sufficient to gain an appreciation of the need for new MRI services.

MRI Service Area means the county or counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide services and in which the majority of its recipients reside. (Revised December 2003)

THA Workgroup Comments: Members attending the 11/07/03 THA Workgroup meeting noted that documentation of patient origin may point to the need to include patient origin by zip code applicable to the proposed service area. At the 12/02/03 session, THA members approved HSDA deputy legal consul advice that the definition of a health care institution's service area mirror that already contained in HSDA rules.

MRI Procedure: A MRI procedure or scan means the gathering of data during a single patient visit from which one or more images may be constructed. The term procedure or scan may be used interchangably; however, the unit of measure is directly related to and verified by the provider's common procedure terminology (CPT) code(s) utilized to document the patient visit. (Revised January 2004)

THA Workgroup Comments: Members at the November & December 2003 THA Workgroup sessions stated that the original definition was confusing and discussed using the term "patient encounter" in lieu of patient session. Review of the definition used in the proposed PET standards provided no fall-back opportunity as this was determined to be confusing as well. At the January 2004 workgroup session, members thought that the original definition would not support volumes that were based upon total number of CPT codes as opposed to patient encounters. As a result, HSDA staff have investigated and have deleted the original draft definition and substituted some of the language (first sentence only) from the Georgia state health plan.
The reasoning is that the Georgia definition appears to be a good fit for the proposed measure of optimal capacity (2,900 MRI procedures per year - as rounded from 2,860 procedures/ year). The 2,900 threshold was developed on the basis of eleven (11) scans per day (8-9 hours in duration) or one (1) scan every 44 minutes, 260 days per year per input from Dan Starnes, MD, who has advised SC-3 on PET and MRI issues. By message to HSDA staff in October 2003, he stated that open or low field strength units are typically limited to approximately 12-15 exams in a 12 hour day (equivalent of 11 exams in an 8.8 hour day), while a high field strength unit can do about 25-28 exams in that time. He defined an exam as one body part – for example a head or neck- and added that more than one exam or body part can be done on one patient at one time. Using this advice, it appears that the proposed definition and the related 2,900 utilization threshold would allow applicants seeking approval for the acquisition of a low field strength unit the opportunity to meet the 2,900 MRI procedure standard, at least on a technological basis.

Optimal Capacity Measures:

Stationary Units: The measure of the optimal number of MRI procedures per MRI unit per year based upon the type of MRI equipment to be used (e.g., stationary, mobile). The optimal capacity for a stationary, fully-operational MRI scanner is 2,900 procedures/year and is based upon a daily operating efficiency of 11 scans per day (or 1 scan every 44 minutes) times 260 days per year. (Revised December 2003)

Mobile Units: The optimal capacity of a fully-dedicated mobile MRI unit at a single host site is 1,200 procedures per year and is based upon an operating efficiency of at least eight (8) procedures/day times 150 days per year. (Revised December 2003)

THA Workgroup Comments: While generally accepting of the rationale for the proposed MRI utilization threshold, members attending the November and December 2003 THA Workgroup sessions recommended that only optimal capacity as opposed to optimal and total capacity be included in the definition. In addition, the members recommended that, in determining capacity, consideration be given to physician practice providers, including Outpatient Diagnostic Centers with MRI owned by and operated by a medical group, who plan to limit the MRI service to use exclusively by its patients. Staff has included language to this effect in Item 4 of the proposed MRI standards (permissible exceptions to standard number of MRI procedures).

Service Area Capacity: The estimate of the number of stationary MRI units needed in a given service area. The estimate must be based upon an optimal capacity of 2,900 procedures/year for a stationary MRI unit. The use of a MRI population-based use rate to predict the number of MRI units needed is encouraged. Applicants shall provide an estimate of the total number of patients who potentially could benefit from MRI diagnostic services, including those patients pertaining to the following categories:

- those patients where the use of MRI services is essential to the diagnosis, treatment or surveillance of multiple organ systems of the human body; and
- those patients who are non-emergent, outpatient candidates for procedures ; and
- any other patient population that may benefit from the accessibility to stationary or mobile MRI services as a result of expanded clinical applications and changes in the reimbursement of MRI services by third party payors, including those pertaining to programs administered by the Center for Medicare and Medicaid Services.

In addition to the above determinants of service area capacity, applicants shall consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. The clinical data must be consistent with that included in the State Health Plan, if available, or with clinical data prepared by the Tennessee Department of Health if data is not available from the State Health Plan. Applicants shall also document the extent, if any, of diagnostic imaging medical services in the proposed service area in its determination of the need for MRI services.

<u>THA Workgroup Comments:</u> members attending the 11/07/03 THA Workgroup meeting suggested that language in the proposed PET definitions pertaining to the documentation of clinical incidence rates and the extent of diagnostic services be used in this definition. The term diagnostic imaging services has been substituted to encompass a broader range of clinical applications for MRI.

<u>PROPOSED MRI STANDARDS:</u>

1. The applicant shall demonstrate that the geographical area comprising the proposed service area has a population and a medical community sufficient to utilize the magnetic resonance device at a rate of 2,900 procedures per year.

   <u>THA Workgroup Comments</u>: Members attending the 11/07/03 meeting recommended that the remarks provided as "Staff Comment" to this item and all standards that follow be removed. The members also suggested that health disparities in lieu of health status be documented to demonstrate clinical need for MRI services.

2. Approval of new MRI services will be made only when it is demonstrated that the existing MRI services in the applicant's geographical service area are performing at an average optimal level of at least 2,900 (*currently stated as 2,200*) clinical procedures per MRI unit per year. No new MRI service shall be approved if the average utilization of existing stationary MRI units is less than 2,900 MRI procedures per year and there exists approved, but unimplemented Certificate of Need approvals for additional new MRI units, whether stationary or mobile, in the service area.

   The calculation for optimal capacity per MRI unit is as follows:

   Stationary Units: 11 procedures/day **x** 5 days/week equals 2,900 procedures/year

   Mobile Units: 8 procedures/day ***x 3*** days/week equals 1,200 mobile MRI procedures/year

   (Revised November 2003; *formula not provided in current standard*)

   <u>THA Workgroup Comments:</u> Members attending the 11/07/03 meeting suggested that the term "new MRI services" be used in lieu of "additional MRI services" in the proposed standard. This language may more accurately reflect that the applicant provider is requesting a new provider service (MRI) in a service area that contains existing MRI providers.

   Members generally agreed with the requirement that no MRI service be approved if there are CON approved but unimplemented MRI services or MRI providers with sub-par utilization in a proposed service area. The members suggested that the standard apply to any provider within the entire proposed service area in lieu of only

those providers within a radius of 45 minutes driving time from the proposed location. Staff revised the standard to include these requirements.

3. The applicant must provide evidence that the MRI equipment is safe and effective for its proposed use.

    a. The United States Food and Drug Administration (FDA) shall certify the proposed equipment for clinical use.

    b. The applicant must demonstrate that the proposed MRI's services will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

    c. The applicant must demonstrate how emergencies within the MRI facility will be managed in conformity with accepted medical practice.

    d. The applicant must establish protocols that assure that all clinical MRI procedures performed are medically necessary and will not unnecessarily duplicate other services.

    e. The applicant must provide supervision and interpretation by a board certified radiologist or physician demonstrating experience and training in the relevant imaging procedure, with certification by the appropriate regulatory body. The MRI service must be under the medical direction of a physician licensed to practice medicine in the State of Tennessee. The applicant shall provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Diagnostic Radiology. Those qualified physicians that provide interpretation services must have additional documented experience and training in MRI technology. Clinical specialty applications of MRI scanning may be interpreted by licensed physicians who have experience, training, credentialing and/or board certification in the appropriate specialty and in the use and interpretation of MRI scans. (Revised January 2004)

<u>THA Workgroup Comments:</u> Members attending the 11/07/03 meeting agreed with the staff recommendation to require interpretation by a licensed Tennessee physician with Board Certification in Diagnostic Radiology. However, the members felt that additional requirements need not limit interpretation to one specialty (Cardiology). Rather, the criteria should be expanded to include all specialties whenever appropriate. Members attending the January 2004 session recommended that the existing criteria for medical supervision and image interpretation be replaced with criteria similar to that developed for the proposed PET standards.

4. Consideration of an exception to the standard number of procedures may be given to applicants organized as a private physician practice, or to Outpatient Diagnostic Center with MRI providers owned by a private practice, who plan to provide the MRI service exclusively to its patients. Consideration may also be given to applicants for MRI services as new or improved technology and equipment or new diagnostic applications for MRI are developed. The applicant must demonstrate that the proposed MRI unit offers a unique and necessary technology for the provision of MRI services in its service area. (Revised December 2003)

THA Workgroup Comments: As noted previously, members attending the 11/07/03 meeting suggested that an exception be considered for MRI services that are operated by physician providers whose use is limited to the physicians and patients of the practice. Staff also included language relative to physician provider applicants that own and operate an ODC who desire to initiate MRI services limited to the use of its patients.

5. Mobile units would not be subject to the need standard in #1 above if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's geographical area are not adequate and/or there are special circumstances that require additional services. (Not Revised)

THA Workgroup Comments: In the staff comments provided for the definition of a mobile unit, staff suggested that the need standard for mobile units in service areas without existing MRI units, including CON approved but unimplemented MRI units, be approved as a minimum of 300 mobile MRI procedures per year. Otherwise, no exceptions of this nature would be necessary. Members will discuss this recommendation at its next workgroup session.

6. Certificate of Need approval for the acquisition of an additional MRI scanner at an existing MRI facility is required when the total cost of the MRI equipment, including the costs to purchase or lease, install, and contract for the routine maintenance of the MRI unit is at or above $1,500,000.00. (Revised December 2003)

THA Workgroup Comments: Members attending the 11/07/03 meeting noted that the current standard is inconsistent with current Statute and should be deleted. This finding is correct. Current statute permits the acquisition of additional MRI scanners by CON approved MRI providers when the cost of the MRI equipment, exclusive of physical plant modifications, is below $1,500,000.00. Staff added clarifying information as to what cost components are considered by HSDA in the calculation of the total cost to acquire the major medical equipment.

Respectfully Submitted,

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